

## REMARKS

This Amendment is submitted in reply to the final Office Action dated November 13, 2009. No fees are due in connection with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00706 on the account statement.

Claims 1-12 and 14-15 are pending in this application. Claims 6-8, 12 and 14-15 were previously withdrawn from consideration, and Claim 13 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112. Claims 1-2, 4 and 10-11 are further rejected under 35 U.S.C. §102 or, alternatively, under 35 U.S.C. §103. Claims 1-5 and 9-11 are rejected under 35 U.S.C. §103. In response, Claims 1 and 9-11 have been amended and Claim 2 has been canceled without prejudice or disclaimer. The amendments do not add new matter and are supported in the specification at, for example, page 5, paragraph 20; page 6, paragraph 32; page 7, paragraph 42; Example 1. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Patent Office asserts that the present specification fails to provide support for the limitation in Claims 1 and 9-11 of a natural lycopene concentrate which “contains no solvent” because a natural lycopene concentrate inherently contains water, which is a solvent. It also appears that the Patent Office takes issue with the use of the phrase “without using a solvent” because Example 1 discloses combining a tomato puree with demineralized water.” See, Office Action, page 2, line 16-page 3, line 2. In response, Applicants have amended Claims 1 and 9-11 to delete the phrase “contains no solvent” and have clarified that the concentrate is in powder form. These amendments do not add new matter. The amendments are supported in the specification at, for example, page 5, paragraph 20.

Further, Applicants respectfully submit that the skilled artisan would immediately appreciate that the phrase “without using a solvent” refers to the use of a solvent for purposes of extraction. Indeed, the skilled artisan would immediately appreciate that the demineralized water

as used in the processes for making the presently claimed compositions is not for the purposes of extraction, but rather alkalization or neutralization. The specification is replete with examples wherein demineralized water is used for alkalization or neutralization of a plant structure, as in Example 1, or a lycopene concentrate. See, e.g., page 5, paragraph 20 (“in the case of the powder, the concentrate is a lycopene powder which is water-soluble at room temperature, this being without using a solvent during the process”); page 5, paragraph 25 (“a plant structure containing a lipophilic compound is alkalized”); page 6, paragraph 34 (“[t]his paste is alkalized with demineralized water”); and page 6, paragraph 39 (“[i]t is possible to bring the pH to neutrality with demineralized water”). Thus, Applicants respectfully submit that the skilled artisan would immediately appreciate that the concentrate is not extracted from a lycopene-containing material using a solvent. Instead, the concentrate is extracted using technological treatments that do not modify the native characteristics of the lycopene. Accordingly, Applicants respectfully submit that Claims 1-5 and 9-11 are fully supported by the present specification.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1-2, 4 and 10-11 are rejected under 35 U.S.C. §102(b) as being anticipated by or, alternatively, under 35 U.S.C. §103(a) as being unpatentable over JP 08336376 to Kawana et al. (“*Kawana*”). For at least the reasons set forth below, Applicants respectfully submit that *Kawana* fails to disclose each and every element of independent Claims 1 and 10-11 and the dependent claims that therefrom.

Currently amended independent Claims 1 and 10-11 recite, in part, natural lycopene concentrates and compositions containing same, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent. The amendments do not add new matter and are supported in the specification at, for example, page 5, paragraph 20; page 6, paragraph 32; page 7, paragraph 42; Example 1. The presently claimed compositions contain natural lycopene concentrates having increased bioavailability. The increased bioavailability may be explained by the smaller size of the concentrate crystals that are obtained during processing. For example, the crystals obtained by

the processes of the present specification are about 5 to 10 sizes smaller than those of the crystalline forms of oleoresin. Additionally, the raw lycopene materials used are more bioavailable because the technological treatments used to obtain the concentrate do not modify the native characteristics of the lycopene. See, specification, page 3, paragraph 7; page 5, paragraph 21. In contrast, Applicants respectfully submit that *Kawana* fails to disclose or suggest every element of the present claims.

For example, *Kawana* fails to disclose natural lycopene concentrates and compositions containing same, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent as required, in part, by independent Claims 1 and 10-11. Instead, *Kawana* is entirely directed to the use of a low-viscosity tomato juice in liquid form, as is admitted by the Patent Office. See, *Kawana*, Abstract; see also Office Action, page 3, lines 24-25.

Further, the Patent Office admits that *Kawana* fails to disclose or suggest the claimed amounts of protein, polysaccharide, organic acid, and lipid compounds, but states that because *Kawana* uses tomatoes to start with, the lycopene concentrate would inherently contain the same amount of each component. See, Office Action, page 4, line 20-page 5, line 3. However, Applicants respectfully disagree and submit that since the technological treatments of the present processes used to obtain the natural lycopene concentrations of the present claims are different from the processes used to obtain the tomato juice of *Kawana*, *Kawana* fails to disclose or suggest the natural lycopene concentrates of the present claims.

Further, to satisfy the test for inherency, the Patent Office would be required to show that *Kawana* necessarily (*i.e.*, always or automatically) provides the amounts of protein, polysaccharide, organic acid, and lipid compounds of the concentrates of the present claims. That condition simply is not met under the present circumstances. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). The Patent Office has failed to provide a basis in fact or any technical reasoning to support any possible determination that the amounts of protein, polysaccharide,

organic acid, and lipid compounds of the concentrates of the present claims are inherent properties of the juice disclosed in *Kawana*.

Moreover, anticipation is a factual determination that “requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. For at least these reasons, Applicant respectfully submits that *Kawana* fails to anticipate the presently claimed subject matter.

Therefore, Applicants respectfully submit that *Kawana* fails to disclose or suggest each and every element of the present claims and, as such, fails to anticipate the present claims or render the present claims obvious.

Accordingly, Applicants respectfully request that the rejection of Claims 1-2, 4 and 10-11 under 35 U.S.C. §102(b) or, alternatively, under 35 U.S.C. §103(a) to *Kawana* be reconsidered and withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Kawana* in view of “Vitamin C content of thirty-six varieties of tomatoes,” *FASEB Journal*, Vol. 7, No. 3-4 (1993) to Hamm et al. (“*Hamm*”) and further in view of JP 200229827 to Uehara et al. (“*Uehara*”). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed previously, currently amended independent Claims 1 and 9-11 recite, in part, natural lycopene concentrates and compositions containing same, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent. The presently claimed compositions contain natural lycopene concentrates having increased bioavailability that may be due to the smaller size of the concentrate crystals and the technological treatments used to obtain the concentrate, which do not modify the native characteristics of the lycopene. See, specification, page 3, paragraph 7;

page 5, paragraph 21. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

For example, *Kawana*, *Hamm* and *Uehara* all fail to disclose or suggest natural lycopene concentrates and compositions containing same, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent as required, in part, by independent Claims 1 and 9-11. Instead, *Kawana* is entirely directed to the use of a low-viscosity tomato juice in liquid form, as is admitted by the Patent Office, see, *Kawana*, Abstract; see also Office Action, page 3, lines 24-25, and *Hamm* is entirely directed to the vitamin C content of varieties of tomatoes, see, *Hamm*, page 4283.

*Uehara* is entirely directed to the cosmetics containing lycopene in an aqueous suspension for external, topical application. See, *Uehara*, Abstract, paragraphs 12 and 31-32. In fact, *Uehara* specifies that the cosmetics may be in the form of lotions, creams, mascara, liquid, ointments and liquid medicines and are used for "external application." See, *Uehara*, paragraphs 31-32. This is in direct contrast to the present claims, which require, in part, natural lycopene concentrates and compositions containing same, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent. For at least the above-mentioned reasons, Applicants respectfully submit that, even if properly combinable, *Kawana*, *Hamm* and *Uehara* fail to disclose or suggest each and every element of the presently amended claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §103(a) to *Kawana*, *Hamm* and *Uehara* be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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